



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUL 25 2000

*Rec'd 8/11/00
Jb*

Ms. Evelyn D. Cadman, CN
Senior Research Scientist
Bioenergy Nutrients
1500 E. 128th Avenue
Thornton, Colorado 80241

Dear Ms. Cadman:

This is in response to your letter of July 14, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Bioenergy Nutrients is making the following claims, among others, for the product Bioenergy Nutrients Vital Systolic™:

- "Promotes healthy blood pressure levels"
- "...promote healthy systolic blood pressure"
- "...support healthy blood pressure in people with high cholesterol"
- "...support healthy blood pressure"
- "...positively affect blood pressure health by helping to promote normal blood pressure levels."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, cure, or mitigate disease, namely, hypertension. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

MS-0163

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-MW240

cc:

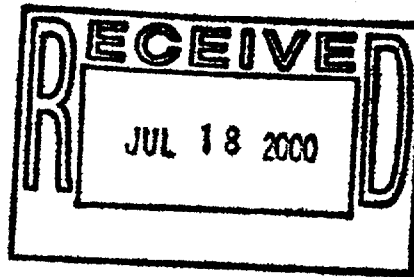
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Nickerson)
f/t:HFS-811:rjm:7/19/00:docname:71576.adv:disc48



Bioenergy Nutrients
1500 E 128th Ave.
Thornton, CO 80241
(303) 474-3104
Fax: (303) 474-2701
www.bioenergynutrients.com

July 14, 2000

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204



NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to § 403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. § 343 (r)(6).

Name of dietary supplement: Bioenergy Nutrients Vital Systolic™

Statement[s] of
nutritional support:

Soothing herbal ingredients for blood pressure health.

Promotes healthy blood pressure levels.

Supports a strong heartbeat.

The hawthorn extract supports vascular integrity and blood flow.

Promotes cardiovascular health.

Olive leaf and hawthorn can support the relaxation of arteries for healthy blood flow.

Hawthorn has been used traditionally as a cardiac tonic.

Hawthorn can enhance coronary circulation.

Hawthorn can support a healthy heartbeat.

Hawthorn can promote healthy systolic blood pressure.

Hawthorn can support healthy blood pressure in people with high cholesterol.

In a preliminary study the combination of hawthorn and passion flower extract has been shown to promote increased physical performance during exercise.

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Bioenergy Nutrients
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Linden flower has been used traditional to help calm the body and support healthy blood pressure.

Passion flower has been used traditionally for calming the nerves

Hawthorn has been used as a heart tonic for centuries

Olive Leaf improves cardiovascular health

Olive leaf has been shown to positively affect blood pressure health by helping to promote normal blood pressure levels.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement[s] is [are] truthful and not misleading. Two copies of this notification are enclosed with this original.

AMRION, INC.

A handwritten signature in black ink, appearing to read "Evelyn D. Cadman, CN". The signature is fluid and cursive, with the initials "CN" written at the end.

Evelyn D. Cadman, CN
Senior Research Scientist